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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,900	02/12/2002	Isabelle Arnould-Reguigne	03806.0537	3572

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EXAMINER	
HUNNICUTT, RACHEL KAPUST	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 11/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/072,900	ARNOULD-REGUIGNE ET AL.	
	Examiner	Art Unit	
	Rachel K. Hunnicutt	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-63* is/are pending in the application.

4a) Of the above claim(s) *10,11,14,15,26-30 and 33-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,12,13,16-25,31,32 and 40-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RESPONSE TO AMENDMENT

Applicant's amendment filed August 16, 2004 is acknowledged. Claims 1-8, 13, 16, 21, 24, and 25 are amended. Claims 41-63 are new. Claims 1-9, 12, 13, 16-25, 31, 32, and 40-63 are under consideration. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections/Objections Withdrawn

The objection to the specification regarding the typographical error on p. 94 is withdrawn in response to the amendment to the specification.

The objection to the specification regarding the use of trademarks is withdrawn in response to Applicant's amendments to the specification.

The objection to claims 16 and 17 under 37 CFR 1.75(c) is withdrawn in response to Applicant's amendment to the claims.

The objection to claim 16 regarding a typographical error is withdrawn in response to Applicant's amendment to the claim.

The rejection of claims 21, 22, 24, and 25 under 35 U.S.C. 101 as being drawn to non-statutory subject matter is withdrawn in response to Applicant's amendments to the claims.

The rejection of claims 1-8, 13, 16-21, and 31 under 35 U.S.C. 112, second paragraph, is withdrawn in response to Applicant's amendments to the claims.

The rejection of claim 5 under 35 U.S.C. 112, second paragraph, regarding the term "high stringent conditions" is withdrawn in response to Applicant's amendment to the claim.

The rejection of claims 2, 5, 7, and 16 under 35 U.S.C. 102(b) as being anticipated by Mahairas *et al.* is withdrawn in response to Applicant's amendments to the claims. Mahairas *et al.* do not anticipate a sequence comprising at least 154 consecutive nucleotides of any one of SEQ ID NOS: 1-4. This rejection may be reinstated if Applicants cancel the limitation in response to the new matter rejection detailed below.

Claim Rejections Maintained/New Grounds of Rejection

Specification

The objection to the specification regarding sequences not found in the sequence listing is maintained for reasons of record on p. 4 of paper no. 0903 mailed on February 24, 2004. The CRF filed on August 16, 2004 was found to be defective, and sequence listing error report was mailed to Applicants on August 19, 2004.

Claim Objections

Applicant is advised that should claim 1 be found allowable, claim 6 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 101

The rejection of claims 1-9, 12, 13, 16-25, 31, 32, and 40 under 35 U.S.C. 101 is maintained for reasons of record on p. 5-7 of paper no. 0903 mailed on February 24, 2004 and applied to new claims 41-63.

Applicants argue that the specification teaches that the ABCA12 protein is associated with pathologies linked to the 2q34 locus of human chromosome 2, particularly the skin disorder lamellar ichthyosis, and thus it can be used in the treatment of such a disorder (p. 13 of response). Applicants argue that "the contention that ABCA12 is associated with this skin

disorder is bolstered by the...data suggesting that ABCA12 is distributed preferably in the skin" (p. 13 of response). Applicants also refer to the post-filing date publication of Lefevre *et al.* who traced the disorder lamellar ichthyosis to five missense mutations in ABCA12 (p. 14 of the response).

Applicants' arguments have been fully considered but have not been found to be persuasive. Even though ABCA12 is associated with lamellar ichthyosis, Applicants have not taught that administering ABCA12 would be useful in the treatment of the disease. One skilled in the art would not know whether administering ABCA12 would be beneficial or whether inhibiting the activity of ABCA12 would be beneficial. Further research would be required to determine if and how ABCA12 would be useful in the treatment of such a disorder.

Even though Lefevre *et al.* confirm that ABCA12 is associated with lamellar ichthyosis, the specification neither teaches nor suggests the missense mutations as taught by Lefevre *et al.* Instead, the specification is completely silent as to using ABCA12 to diagnose lamellar ichthyosis. Teaching that ABCA12 is associated with a disease is not the same as saying that it causes a disease and can be used to diagnose lamellar ichthyosis.
See *In re Kirk*, 153 USPQ 48, 53 (CCPA 1967) quoting the Board of Patent Appeals,

> We do not believe that it was the intention of the statutes to require the Patent Office, the courts, or the public to play the sort of guessing game that might be involved if an applicant could satisfy the requirements of the statutes by indicating the usefulness of a claimed compound in terms of possible use so general as to be meaningless and then, after his research or that of his competitors has definitely ascertained an actual use for the compound, adducing evidence intended to show that a particular specific use would have been obvious to men skilled in the particular art to which this use relates.

Claim Rejections - 35 USC § 112

The rejection of claims 1-9, 12, 13, 16-25, 31, 32, and 40 under 35 U.S.C. 112, first paragraph, is maintained for reasons of record on p. 7 of paper no. 0903 mailed on February 24, 2004 and applied to new claims 41-63. Since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The rejection of claims 2-5 under 35 U.S.C. 112, first paragraph, for lack of enablement, is maintained for reasons of record on p. 8-9 of paper no. 0903 mailed on February 24, 2004 and applied to new claims 41-51.

Applicants argue that the specification teaches methods for producing ABCA12 derivatives and that such techniques are well known in the art (p. 14 of response).

Applicants' arguments have been fully considered but have not been found to be persuasive. The claims are drawn to nucleic acid sequences comprising fragments of any one of SEQ ID NOS: 1-4 and sequences which are at least 80%, 90%, 95% or 98% identical to any one of SEQ ID NOS: 1-4. Even if the specification provided support for diagnosing lamellar ichthyosis with ABCA12, the skilled artisan would not know how to use nucleic acid sequences comprising fragments of any one of SEQ ID NOS: 1-4 or sequences that are at least 80%, 90%, 95% or 98% identical to any one of SEQ ID NOS: 1-4 for diagnosing lamellar ichthyosis. The claims have no functional limitations, and such nucleic acid sequences could encode polypeptides with functions that vary greatly from that of ABCA12. The specification does not teach the skilled artisan how to make derivatives of ABCA12 that have the same function as ABCA12.

Due to the large quantity of experimentation necessary to generate the large number of nucleic acid sequences recited in the claims and screen the same for activity, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of mutation on protein structure and function, and the breadth of the claims which fail to recite any functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention.

The rejection of claims 2-5 under 35 U.S.C. 112, first paragraph, for failing to comply with the written description requirement, is maintained for reasons of record on p. 9-10 of paper no. paper no. 0903 mailed on February 24, 2004 and applied to new claims 41-51.

Applicants argue that the specification provides four examples of ABCA12, and preparing a nucleic acid comprising a sequence having at least 80-98% identity with any one of SEQ ID NOS: 1-4 would be readily apparent to one of ordinary skill in the art (p. 15 of response).

As previously stated, the claims do not have any functional limitations. In addition, the specification does not provide a utility or function for ABCA12. The claimed nucleic acid sequences may have functions and structures which differ greatly from that of ABCA12, therefore one of skill in the art would not be able to predictably identify the encompassed molecules as being identical to those instantly claimed.

Claims 2, 5, 7, 9, 13, 16, and 17 are newly rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 2, 5, 7, 9, 13, 16, and 17 encompass nucleic acid sequences comprising at least 154 consecutive nucleotides of any one of SEQ ID NOS: 1-4 or nucleic acid sequences at least 154 nucleotides in length that hybridize to any one of SEQ ID NOS: 1-4. However, nowhere in the specification is there any mention requiring sequences to be 154 nucleotides in length or requiring homologous sequences to comprise at least 154 consecutive nucleotides of any one of SEQ ID NOS: 1-4. There is no written support for the claimed nucleic acid sequences. Such nucleic acid sequences are considered to be new matter.

Claims 1-9, 12, 13, 16-21, 31, and 41-63 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject

matter which applicant regards as the invention. As written, claims 1-8, 16, and 41-43 are drawn to "a nucleotide sequence complementary along its entire length to any one of SEQ ID NOS: 1-4". Due to the way the claims are written and the placement of the comma, the claims all appear to be drawn to sequences that are full-length complements of SEQ ID NOS: 1-4. It appears, however, that Applicants intend to have the sequences be complementary to the sequences detailed in the first part of the claims. This rejection could be obviated by amending the claims to read "an isolated nucleic acid comprising at least 154 consecutive nucleotides of a nucleotide sequence of any one of SEQ ID NOS: 1-4 or a full-length complement thereof" (see claim 2) or "an isolated nucleic acid comprising a nucleic acid sequence that has at least 80% nucleotide identity with a nucleic acid comprising any one of SEQ ID NOS: 1-4 or a full-length complement thereof". Claims 9, 12, 13, 17-21, and 44-63 are rejected as being depending on claims 1-8, 16, and 41-43.

Claims 48-51 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 48-51 are dependent on claim 5, which is drawn to an "isolated nucleic acid at least 154 nucleotides in length". Claims 48-51 are drawn to the isolated nucleic acid according to claim 5, wherein the nucleic acid comprises at least 200, 500, 1000, or 1500 consecutive nucleotides. There is no mention of consecutive nucleotides in claim 5. It is not clear whether Applicants intend to mean an isolated nucleic acid at least 200, 500, 1000 or 1500 nucleotides in length or if Applicants are suggesting that the nucleic acid sequence must hybridize to at least 200, 500, 1000 or 1500 consecutive nucleotides of any one of SEQ ID NOS: 1-4.

Claim Rejections - 35 USC § 102

Claims 2, 5, 7, 16, 44, 45, 48, 49, 52, 53, 60, and 61 are rejected under 35 U.S.C. 102(b) as being anticipated by Ansorge *et al.*, GenBank Accession No. AL080207. Claims 2, 7, 44, 45, 52, and 53 are drawn to a nucleic acid sequence comprising at least 154, 200 or 500 consecutive

nucleotides of any one of SEQ ID NOS: 1-4. Claims 5, 48, and 49 are drawn to a nucleic acid sequence comprising at least 154, 200 or 500 nucleotides which hybridizes to any one of SEQ ID NOS: 1-4. Claims 16, 60, and 61 are drawn to kits for detecting nucleic acid sequences, wherein the kit comprises a nucleotide probe comprising at least 154, 200 or 500 consecutive nucleotides of any one of SEQ ID NOS: 1-4. Ansorge *et al.* teach AL080207, which is 100% identical to SEQ ID NO: 4 over a span of 617 nucleotides (see attached alignment). Thus, Ansorge *et al.* anticipated claims 2, 5, 7, 16, 44, 45, 48, 49, 52, 53, 60, and 61. The kit of claims 16, 60, and 61 is merely an intended use.

Conclusion

NO CLAIMS ARE ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel K. Hunnicutt whose telephone number is (571) 272-0886. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RKH
11/8/04

JANET ANDRES
PRIMARY EXAMINER